1.0 Purpose and Scope

1.1 This procedure describes the process used to review, report and release data collected by headspace GC analysis in determining the presence and concentration of ethanol in evidentiary blood samples.

2.0 Responsibility

2.1 It is the responsibility of all analysts assigned to perform this procedure to follow it as written. In the event that there are changes to be made to this procedure, the analyst must report those changes in detail to the Alcohol Program Supervisor in a timely manner. This procedure is reviewed periodically for completeness and accuracy.

2.2 The analyst is responsible for assembling the data package and delivering it to the assigned reviewer in a timely manner.

3.0 Precautions

3.1 The staff responsible for data review must ensure that the data package is complete and that the report forms are properly reviewed, accurate and signed by the analyst.

3.2 Staff responsible for data review must ensure that all sample and log data are examined for accuracy and completeness. All hand calculations must be confirmed.

4.0 Procedure

4.1 Upon successful completion of analysis, the analyst must perform a primary data review of their package prior to submitting the complete package to the assigned reviewer for technical review.

4.2 The complete data package includes:

4.2.1 The Blood Alcohol Data Review Checklist (F-ALC 011).

4.2.2 All chromatograms generated during the analytical process.

4.2.3 The ethanol calibration line graph and data.

4.2.4 The analytical run schedule.

4.2.5 The Headspace Alcohol Analysis Standards Coversheet (F-ALC 010).

4.2.6 An Evidentiary Blood Alcohol Report for each sample.

4.3 Analyst Review

4.3.1 Review the calibration line for a correlation coefficient of at least 0.99x, a percent error of less than 10% and the individual calibration standards for recoveries within ± 10% of their known values.

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4.3.2 Review the timing mix chromatogram for retention time separation of the timing mix compounds from ethanol. All compounds should be represented by separate peaks with no coelution.

4.3.3 Ethanol in the Blank must show quantitation of <0.005g/dL.

4.3.4 Review the percent recovery of the whole blood ethanol control for recovery within ± 10% of its target value.

4.3.5 Review individual analytical results of submitted samples. Ensure that each result is within ± 10% of the mean of the two replicates for that sample. If not, an additional two aliquots of the sample are analyzed. The number of samples used to report the average will be determined on a case by case basis.

4.3.6 Ensure that all samples are quantified against the correct calibration version as listed on the calibration report.

4.3.7 Review all calibration check sample data. Each result should be within ± 10% of the mean of the two replicates. An exception to this is if one replicate has recovery of less than 10% or greater than 150%, which would be indicative of preparation error. In this case, the remaining replicate can be used as a valid calibration check.

4.3.8 Perform all calculations and ensure that proper rounding rules have been followed.

4.3.8.1 Individual sample results are recorded to three decimal places in the report.

4.3.8.2 If the fourth value to the right of the decimal is 7 or greater, round up. If it is less than 7, truncate.

4.4 Technical Review:

4.4.1 The assigned reviewer must perform a review of the complete data package as described in 4.3.1 to 4.3.8.

4.4.2 Ensure that the forms are complete and accurate.

4.4.3 When data review is complete and no data quality issues have been identified, the reviewer notes on the data review check sheet his/her initials and the date reviewed.

4.4.4 If data quality issues have been identified during data review, the reviewer must attempt resolution through discussion with the analyst and/or program supervisor. If issues can not be resolved, it may be necessary to prepare and analyze new aliquots of the submitted sample.

5.0 Non-Routine and High Priority Situations

5.1 The Commissioner of Public Safety, Laboratory Director or Alcohol Program Supervisor may designate samples as high priority.

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5.2 In the case of a high priority situation, the analyst, the reviewers and administrative assistant will coordinate to expedite the analysis, review and reporting of the high priority samples.

5.3 High priority sample results will be analyzed, reviewed and reported as soon as reasonably possible.

6.0 Quality Control and Corrective Action

6.1 In order for a data package to pass quality assurance all of the review criteria must be met.

6.2 Apparent errors and/or omissions are noted at the bottom of the Blood Alcohol Data Review Checklist (F-ALC 011) and referred to the analyst for resolution. The reviewer assesses the need for corrective action and either returns the data to the analyst for further resolution or releases the data.

7.0 Back-up

7.1 In the absence of the analyst, errors or omissions can be referred to the Alcohol Program Supervisor. The Supervisor will identify needed corrective action and assign staff to implement the action.

7.2 If the scheduled reviewer is not available, the analyst can request data review from any other qualified analyst or the Alcohol Program Supervisor.

8.0 References and Appendices

8.1 Blood Alcohol Data Review Checklist (F-ALC 011).

8.2 Headspace Alcohol Analysis Standards Coversheet (F-ALC 010).

8.3 Request for Analysis for Alcohol/Drugs in Blood (F-ALC 001 or F-ALC 001 DRE or 305).

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